510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The *NexGen®* Primary Porous Patella

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Robert Poggie
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Date Prepared:	June 11, 2001
Device Trade Name:	The *NexGen* Primary Porous Patella
Device Common Name:	Patellar Components
Classification Number and Name:	21 CFR § 888.3560

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The *NexGen* Primary Porous Patella is manufactured from Trabecular Metal (Hedrocel Porous Tantalum) with direct compression molded ultra-high molecular weight polyethylene (UHMWPE). The Primary Porous Patella is available in two options: Micro and Standard.

These patellar components are intended for use with Zimmer *NexGen* Femoral components.

510(k) Summary (Continued)

Indications for Use:

The *NexGen®* Primary Porous Patellar components are intended as a patellar component whose indications for use include:

1) Non-inflammatory degenerative joint disease including osteoarthritis or traumatic arthritis, 2) rheumatoid arthritis, 3) correction of functional deformity, 4) revision procedures where other treatments or devices have failed, and 5) treatment of fractures that are unmanageable using other techniques. This device is intended for use with bone cement.

Conclusion:

The *NexGen®* Primary Porous Patella (Micro and Standard) is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2001

Robert A. Poggie, Ph.D.
Director of Applied Research
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K011904
Trade Name: *Nexgen*® Primary Porous Patella
Regulation Number: 21 CFR 888.3560
Regulatory Class: II
Product Code: JWH
Dated: June 18, 2001
Received: June 19, 2001

Dear Dr. Poggie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011904

Device Name: The *NexGen®* Primary Porous Patella

Indications For Use:

The *NexGen®* Primary Porous Patella is intended as the patellar component whose indications for use include:

1) Non-inflammatory degenerative joint disease including osteoarthritis or traumatic arthritis, 2) rheumatoid arthritis, 3) correction of functional deformity, 4) revision procedures where other treatments or devices have failed, and 5) treatment of fractures that are unmanageable using other techniques. This device is intended for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Donna Chelle for CDRH

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use (Per 21 CFR 801.109) X

OR...

510(k) Number K011904 Over-the-Counter Use

(Optional Format 1-2-96)